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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,449	09/21/2001	Troy Holland	BioCure 161	5786

27029 7590 12/18/2002

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,449	HOLLAND ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' declaration, filed 01/10/2002.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6, 9, 12, 13, 19, 22, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 6 and 19, the claims are indefinite because it is not set out if the macromers recited in claims 6 and 9 are the same of claims 5 and 18, respectively, or the composition comprising another macromer?

Regarding claims 9 and 25, the phrases in between parentheses as well as the abbreviation "e.g." rènder the claims indefinite because it is not certain whether the bracketed limitation(s) or limitation(s) following the "e.g." are part of the claimed invention. See MPEP § 2173.05(d).

Claim 12 recites the limitation "water soluble macromer" in claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "*in situ* crosslinking" in claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "*in situ* polymerization" in claim 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of an application filed in the United State only if the international application designating the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6, 8, 9, 14-17, 19, 21, 22, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 560 014 ('014).

EP '014 disclosed a biodegradable wound dressing that can include therapeutic agent delivered to human tissue by spraying the film forming formulation into the tissue or wound (abstract; col.4, lines 23-30; col.23, lines 51-58). The film is formed from liquid composition comprising polymer that dispensed or sprayed onto the tissue site and solidifies *in situ* on the tissue and converts into film or gelatinous matrix (col.1, lines 48-58; col.3, lines 1-9; col.4, lines 15-17). The composition comprises polymer; plasticizer (wetting agent); and biologically active agent including antimicrobial agents, anti-

inflammatory agents, analgesics, and growth factors such as PDGF, EGF, and TGF (col.2, lines 50-53; col.11, lines 40-56; col.12, lines 20-41). The dispensing means can be aerosol or pump (col.4, lines 20-48). The claimed composition is anticipated by EP '014.

5. Claims 1, 3, 4, 8, 9, 14, 16, 17, 21, 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,495,168 ('168).

US '168 disclosed a pressurized composition in an aerosol container adapted to form spray upon release of the pressure therefrom, which composition is liquid inside the container and forms gel on contact with the living tissue. The composition comprising polymer, skin treating agents, and adjuvant. The composition comprises antibiotics and glycerin, i.e. wetting agent. (col.5, lines 1-7, 25). The claimed composition is anticipated by US '168.

6. Claims 1-8, 13-21, 25, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,179,862 ('862).

US '862 disclosed method and composition for forming *in situ* tissue adherent barrier using sprayer to apply cross-linkable component to the tissue (abstract). When the sprayer is activated, the emergent spray contacts tissue, resulting in mixing and cross-linking of the components to form coating, e.g. hydrogel, on the tissue surface (col.2, lines 5-9). The components are in the form of solution and comprise water-

soluble, crosslinkable, biodegradable macromers (col.2, lines 19-34; col.7, lines 24-30). The composition comprises bioactive drugs (col.3, lin3s 35-36). The hydrogel is formed by gelation or precipitation of the polymeric solution and initiated by redox (col.4, lines 24-27; col.6, lines 3-5). The claimed composition is anticipated by US '862.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of EP '014, US '168 or US '862.

The teachings of the references are discussed above. The references do not teach NO as an active agent, debriding the wound when the dressing is removed, or the PVA macromer.

It is within the skill in the art to determine the biologically active agent to be included in the wound dressing according to particular need. No criticality has been established in using NO in the composition of the wound dressing. PVA is inherently a crosslinkable biodegradable macromer, and no criticality was shown in its use in particular. The references teach the sprayable composition as an adhesive, thus it will debride the wound upon its removal.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a wound dressing formed *in situ* by spraying a formulation comprising macromer and select the active agent to be included in the spray composition according to the patient need with reasonable expectation of success of the delivered dressing in treating wounds and debriding the underlying tissue when needed.

10. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of EP '014, US '168 or US '862 in view of US 5,410,016 ('016).

The teachings of the references are discussed above. The references do not teach NO as an active agent, debriding the wound when the dressing is removed, or the PVA macromer.

It is within the skill in the art to determine the biologically active agent to be included in the wound dressing according to particular need. No criticality has been established in using NO in the composition of the wound dressing. The references teach the sprayable composition as an adhesive, thus it will debride the wound upon its removal.

US '016 teaches a hydrogel of biodegradable, polymerizable, crosslinkable, water soluble macromers used for protection of the tissue surfaces, i.e. dressing (abstract; col.4, lines 29-31). The macromers form hydrogel *in situ* when applied to the tissue (col.5, lines 65-68; col.6, lines 16-17). The macromers comprise PVA and antibiotics (col.8, line 42; col.10, lines 29-35).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a wound dressing formed *in situ* by spraying a formulation comprising macromers as taught by any of EP '014, US '168 or US '862 and select PVA as a macromer as disclosed by US '016, motivated by the teaching of US '016 that the hydrogel comprising macromers such as PVA can be administered during surgery and out-patient procedures and polymerized as tissue adhesive or drug delivery of anti-angiogenic agents, and select the active agent to be included in the spray composition according to the patient need, with reasonable expectation of success of the delivered dressing in treating wounds and debriding the underlying tissue when needed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600